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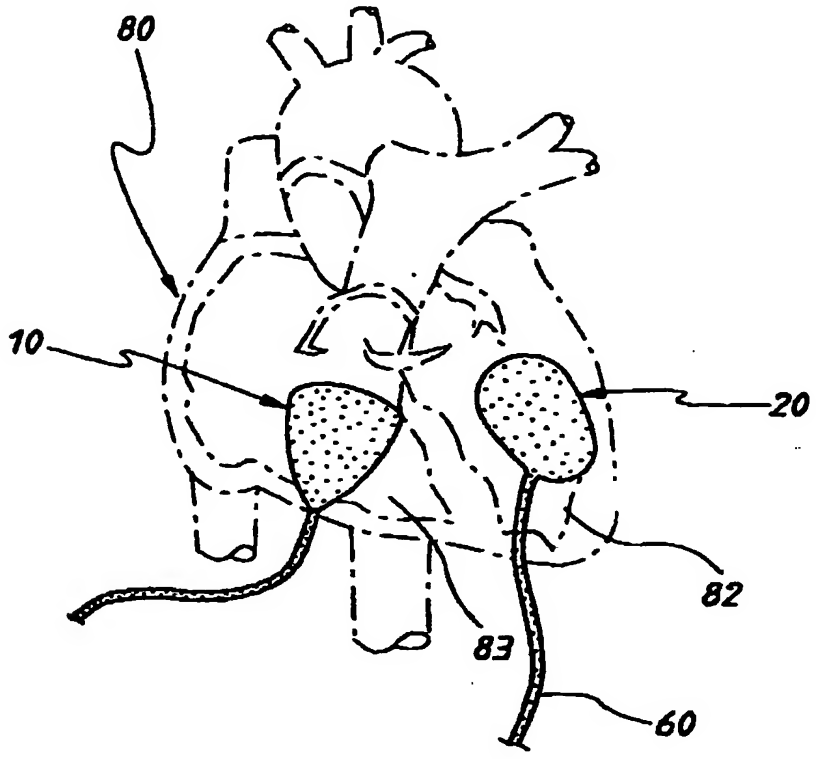

(57) Abstract: A heart actuator device for use in heart assist apparatus, which device includes a paddle-like main body. The main body has a heart compressing wall, which in use is adapted to be affixed to at least a region of the heart, and a distal wall, which in use is adapted to be distal that region of the heart. The heart compressing wall is movable in a direction relatively away from the distal wall, so as, in use to compress at least that region of the heart thereby assisting movement of the heart wall.

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AN ASSIST DEVICE FOR THE FAILING HEART

Field of the Invention

The present invention relates to a device and method for assisting a failing heart.

Background Art

Cardiac compression has been used to boost a failing heart for many years and in its most simple life-saving form involves the compression of the chest wall of a patient. In an emergency situation, a surgeon may take this one step further by manually compressing a heart that has failed, until recovery or an alternative treatment is instituted.

Of course, not all patients present in an acute state and typically a heart will be damaged over a period of time. This can also result in heart failure, a situation which occurs when the heart fails to maintain sufficient circulation of blood to provide adequate tissue oxygenation. Heart failure is widespread in the community affecting for example, 5 million Americans at any one time. Despite recent advances in cardiology, it remains on the increase.

Mechanical heart assist devices that can be used to boost an ailing heart have the potential to provide a quality of treatment that seriously challenges current treatment options, including heart transplantation. Whilst heart transplantation is effective in patients with severe heart failure, the shortage of donor hearts, the expense of the operation and post-operative care, and the risk of rejection are major drawbacks to this option ever fulfilling community expectations.

Several mechanical devices have been developed, one of which is the subject of US Patent No. 5119804 to Anstadt. This device comprises a cardiac massage cup adapted to fit loosely over a lower portion of a heart. A diaphragm is positioned internal the cup and positive and negative pressure applied to the space between the diaphragm and the cup to

alternately inflate and deflate the diaphragm. When the diaphragm is inflated, the heart is squeezed to assist systolic action (ejection of blood from the ventricles of the heart). The diaphragm is deflated to correspond with diastole (relaxing of the heart muscle and filling of the heart pumping chambers with blood). The cup itself is held in place around the heart by a suction force which prevents the heart from dislodging when compressive pressure is applied to the heart.

The requirement that the diaphragm be set inside a cup results in a bulky device which may also cause damage to the heart muscle, coronary circulation and the surrounding tissue.

Variations of the Anstadt cup have been developed including the device subject of US Patent No. 5713954 which describes a cuff to enclose the lower regions of the heart. The cuff comprises a series of closed tubes which may be hydraulically or pneumatically inflated in synchrony with the natural contractions of the heart to reinforce the contractile force required to eject sufficient blood for the needs of the body. Literature reports have shown the enhancement of heart pumping by other currently described cardiac compression devices to be limited to between 10 and 15%.

A drawback of several assist devices is that the right and left ventricular pumping action of the heart is simulated using a single diaphragm. It is well recognised, however, that differences exist between right and left ventricular output and that right and left ventricular pressures are different. Essentially, because the left ventricle is ejecting blood to the entire body it requires a greater force of contraction. Devices with only one diaphragm will not assist to provide optimum output of either the right or the left ventricle. A device designed to address this problem is described in US Patent No. 5749839 to Kovacs wherein the assist device is provided with two independently operated diaphragms within a cup to allow for independent control of the left and the right ventricles. This device does not seem, however, to take into account the difference in curvature between the surface of the left-and right ventricles and uses a diaphragm of the same shape for both

ventricles. This would seem to potentially result in a misfit of the device over the heart if used in this manner.

With the cardiac assist devices described above, there must be a means for securing the device to the external surface of a heart. Securement may be achieved by applying suction through a vacuum line, such as is the case in the Anstadt device, wrapping the device in a passive mesh which may be fitted around the heart, by suturing or by some form of adhesive. Whichever means is employed, there is a risk of damage to the heart and in particular to the coronary circulation which is made up of a network of blood vessels that traverse the outer surface of the heart.

In International Application No. PCT/AU98/00433 (WO 98/55165) entitled "Cardiac Assist Device", a device comprising a cup and an internal diaphragm wherein at least a portion of the diaphragm is made from a biointegrating material is described. This device is designed to maximise affixation of the device to the heart by enabling vascularised tissue infiltration into the device. Preferably, the biointegrating material of the diaphragm integrates with the surface of the heart muscle to such an extent that a vacuum or other such means of securement is not required. It is believed that the use of a biointegrating material on the surface of the diaphragm minimises the risk of infection, and rejection of the device by the host's defence system. The device is reliant, however, on a bulky, cup-like structure and requires traditional surgical technique for placement. Such devices may also constrict the heart causing impairment of its filling and proper relaxation. This may also impede blood supply to the heart muscle via the coronary circulation.

Disclosure of the Invention

According to one aspect of the present invention there is provided a heart actuator device for use in heart assist apparatus, the device including a paddle-like main body, the main body including a heart compressing wall, which in use is adapted to be affixed to at least a region of the heart, and a distal wall, which in use is arranged to be distal that region of the heart, and the heart compressing wall being movable in a direction relatively

away from the distal wall, so as, in use to compress at least that region of the heart thereby assisting movement of the heart wall.

In one preferred form, the paddle like main body includes two major walls secured to or integral with each other at the peripheral portions thereof, one of the major walls defining the heart compressing wall and the other defining the distal wall. Preferably, the heart compressing wall includes a heart compressing surface which is generally curved inwardly towards a central region of the main body when in a normally relaxed condition. Preferably, the distal wall has a distal surface which is curved outwardly when in a normally relaxed condition.

The device may further include a chamber within the main body between the heart compressing wall and second distal wall and which is adapted for the ingress or egress of fluid which causes the movement of the heart compressing surface.

In a preferred form, the main body is configured such that both the heart compressing wall and the distal wall are adapted to move in a direction relatively away from one another.

Preferably, the heart compressing wall and the distal wall of the main body are of the same material with different degrees of stiffness. In one preferred form, the distal wall, the outer rim of the compressing wall and the portion joining the compression wall and distal wall edges include a reinforcing material therein to provide for a greater degree of stiffness and durability relative to the heart compressing wall. The strength of the distal wall, which does not have the added support that is provided to the compressing wall by the heart wall when the paddle is inflated, is thus also enhanced.

According to one preferred embodiment, at least a portion of the heart compressing wall includes a biointegratable material surface which facilitates the ingrowth of vascularised cellular tissue elements on the wall, the ingrowth of tissue into the heart compressing wall serving to affix the heart compressing wall of the main body to the heart.

Desirably, the distal wall includes a biointegratable material that promotes vascularised cellular ingrowth into the distal wall which is thus adapted to integrate into surrounding tissue. The biointegratable material may for example be in the form of woven Tecoflex™ mesh, Seare Biomatrix™ or Gore-Tex DualMesh Biomaterial ™.

In one preferred form, the paddle-like main body is deformable so as to be capable of undergoing a change from a first configuration to a second configuration. Preferably, the paddle-like main body includes a shape memory material which permits said deformation and subsequent return to its original shape.

Preferably, the main body includes a unitary structure formed of polyurethane, silicone or any other suitable material.

According to a preferred embodiment, the device may include means to monitor the cycle of a heart. The device may for example be adapted to be activated during systole or diastole of the heart. The monitoring means may include an electrocardiogram electrode operatively connected to at least a region of the surface of a heart and the electrical signals received from the electrodes transmitted to a cardiotachometer for the detection of heart rate, beat-to-beat interval or other native electrical activity of the ventricles..

The device according to a preferred embodiment may include one or more sensors adapted to measure the heart dimensions and excursion of the paddle walls during the cardiac cycle. Preferably, the or each sensor is a piezoelectric sensor. One example of a preferred form of sensor is a sonomicrometer. Preferably, there are a plurality of sensors operatively connected in selective positions to the heart compressing wall.

In a preferred form, the heart compressing wall is configured so that the heart compressing surface generally conforms to the shape of that region of the heart to which it is fixed.

The heart compressing wall may be adapted to be affixed to a region of either the left ventricle and/or the right ventricle of the heart.

According to another aspect of the present invention there is provided heart assist apparatus including one or more heart actuator devices as described above which are adapted to be secured to a region or selected regions of the heart, said apparatus further including driving means in fluid communication with the chamber. Preferably, there is provided a plurality of said heart actuator devices operatively connected to selected regions of the heart.

Preferably, the driving means is a hydraulic driving means. In another form it may be a pneumatic driving means.

In a preferred embodiment, the heart compressing wall is adapted to remain affixed with at least the aforementioned region of the heart regardless of any variation in the heart's condition. As described, previously known devices for assisting a failing heart have relied upon the principle of partially encasing at least the lower regions of a heart in a cup or other similarly rigid device. Internal the cup, such devices have a membrane or diaphragm which may be activated to compress the heart. One problem associated with such devices is related to obtaining the best fit of the device to a heart that is already enlarged and flaccid. When the heart is so enlarged, the device in being placed around the heart can create a situation similar to constrictive pericarditis or cardiac tamponade, conditions which can cause severe impairment of the heart's pumping action due to external restriction that compromises filling of the blood chambers. This condition is likely to worsen when a layer of fibrous tissue is caused to grow around the heart because of a tissue reaction in response to the surrounding foreign material. When the device is of such a size that the heart is fitted too loosely in the cup, the pumping action of the diaphragm acts to thump the surface of the heart during systolic assist. This poses a threat of bruising the heart and is also energetically highly inefficient.

According to available evidence from clinical and experimental use of mechanical cardiac assist devices, it is likely that the heart will become smaller (a process termed reverse remodelling of the heart) as a result of their use. This process involves some recovery of the muscle cells of the heart allowing the heart chambers to revert towards a more favourable pumping geometry. With use of a rigid cup employing a one piece diaphragm or several linked chambers to secure compression of the heart, reverse remodelling is unlikely to be facilitated even if the diaphragm is affixed to the heart. Further, if the diaphragm is affixed to the heart with this implementation, it is likely to hinder any residual contraction of the native heart.

On the other hand, using one or more devices according to the invention and affixing the heart compressing wall thereof to the heart surface in a manner that does not hinder the normal contractile geometry of the ventricles, accommodates the improvement in heart condition that occurs with reverse remodelling. Means of affixing the heart compressing surface to the heart surface are discussed in more detail below.

In one embodiment, a majority and in some cases the entire heart compressing wall may be affixed to the aforementioned region of the heart.

As mentioned, the shape of the devices can be configured to suit the region of the heart to which the device is to be affixed.

As discussed earlier the heart compressing wall and/or the distal wall can be curved relative to a notional lateral and/or longitudinal plane. The curvature is preferably selected to suit the curvature of the region of the heart to which it is to be affixed. According to yet another aspect of the present invention there is provided a method of assisting a failing heart using a heart actuator device as described above, the method including the steps of:

(a) positioning the heart compressing wall of the device at least adjacent a region of the heart;

(b) affixing the heart compressing wall to the region of the heart: and

(c) applying fluid pressure to the chamber of the device such that the heart compressing wall compresses the heart wall in the region of the heart to which the device is affixed.

According to yet another aspect of the present invention there is provided a method of introducing a device as described above to the heart of a patient, the method including the steps of:

(a) making an incision or puncture in the chest of a patient to allow access to the heart;

(b) inserting the device through the incision or puncture;

(c) affixing the heart compressing wall of the device to a region of the heart; and

(d) applying fluid pressure to the chamber of the device such that the heart compressing wall compresses the heart wall in the region of the heart to which the device is affixed.

In one embodiment of this aspect of the invention, the device is inserted by firstly inserting a cannula through a port in the body and then passing the device through the cannula. In this embodiment, the device is preferably in a first closed configuration at least while it is internal the cannula. When positioned adjacent the region of the heart with which the paddle is to be affixed, the paddle is ejected from the cannula by a push rod or other like device whereupon it can take on a second expanded configuration. The cannula can then be withdrawn through the port before it is in turn removed.

In another embodiment of this aspect of the invention, the device may initially be held in place by a covering means such as a mesh that will wrap around the paddle and the heart. If desired, a suitable tissue glue can also be used to either affix the heart compressing surface to the heart or to enhance affixation provided by the covering means. Once sufficient cellular ingrowth has occurred, the covering means may be removed from around the heart. Alternatively, the covering means may be made from a biocompatible resiliently flexible material which may remain in place around the heart and the paddle. It is important that the covering means is made from a suitable flexible material, however, to

allow for any change in the heart's condition, including variation in its size, shape or configuration. In a still further embodiment, the covering means may be made from a biodegradable material that is progressively resorbed by the body over a period of time.

The device in all aspects of the invention is preferably adapted such that it may be introduced into the patient and proximate the heart using minimally invasive or endoscopic surgery. It will, however, be appreciated that the device may be introduced through a thoracotomy.

Brief Description of the Drawings

Preferred embodiments of the invention will hereinafter be described with reference to the following drawings:

Figure 1 is a schematic representation of a heart with two devices according to the present invention in position against the surface of the heart.

Figure 2 is a perspective view of one form of the device according to the invention.

Figure 3 is a cross-sectional view through X-X of Figure 4 depicting the device of the invention in a collapsed state.

Figure 4 is a schematic front elevational view of the device of the invention.

Figure 5 is a schematic front elevational view of another embodiment of the invention.

Figure 6 are tracings of physiological parameters showing the effect of the device of the present invention on both a normal and a failing heart.

Best Mode of Carrying out the Invention

Referring to Figure 1 of the drawings there is shown a part of a heart assist apparatus applied to a heart 80 having a left ventricle 82 and a right ventricle 83. The apparatus shown includes two heart actuator devices 10 and 20, one of which is affixed to the right ventricle 83 and the other is affixed to the left ventricle 82 of the heart 80. As best seen in Figures 4 and 5 the devices 10 and 20 for affixing to the right and left ventricles of the heart differ in configuration but are generally of the same structure.

Referring to Figures 2 to 4 of the drawings, there is shown one embodiment of the heart actuator device which is particularly suited for attachment to the right ventricle. The heart actuator device 10 which comprises a paddle-like body 11 having a heart compressing wall 12 which is adapted to be affixed to a region of the surface of the right ventricle of the heart and a distal wall 13 which is positioned distal the surface of the heart. As shown in Figures 2&3 the device 10 is generally triangular in shape with walls 12 and 13 being in the form of major walls joined by a peripheral edge portion 17. As best seen in Figure 3 both of the walls 12 and 13 are curved. This is particularly advantageous insofar as the heart compressing wall 12 is concerned because the curved nature of the wall inhibits stretching of the wall during movement thereof as described below.

The walls 12 and 13 have a chamber 15 therebetween, the chamber 15 being in fluid communication with a driver (not shown) which generates either hydraulic or pneumatic pressure. When the driver is activated pressure builds up in the chamber 15 causing both walls 12 and 13 to be moved relatively away from one another. The driver, controller or powersource can be positioned either internal or external the body of a patient receiving the device 10.

Chamber 15 is in fluid communication with the driver by way of tube 60 which is made from a suitably resiliently flexible material to facilitate insertion of the device 10 into the chest cavity of a patient whist still maintaining its tubular shape. This is a most desirable feature as any kinking of the tube would block the communication between

chamber 15 and the driver thereby preventing the application of pressure to the walls of the device.

The body 11 of the device has a reinforcing mesh 18 incorporated primarily into the distal wall 13. As best seen in Figure 3 the mesh 18 extends around the region of the peripheral portion 17 into the heart compressing wall 12.

The walls 12 and 13 have thereon a layer of biointegrating material 16 which facilitates the ingrowth of vascularised cellular tissue elements into the device. The cellular ingrowth of tissue secures the device to the surface of the heart avoiding the need to use suturing or various adhesives. In addition to securing the device to the surface of the heart, the likelihood of rejection of device by the heart and surrounding tissue is also reduced. The biointegration of the heart tissue with the device is also an advantageous feature for transmission of biopotential information such as the heart's electrical activity to the electrode 30 located in the wall 12 of the device, and for transmission of the ultrasound signals gathered from the piezoelectric sensors or sonomicrometers 31, 32, 33. Furthermore, because the heart tissue biointegrates with the device there is a markedly lessened chance of 'fibrous capsule' formation and the incidence of infection is greatly reduced. This is particular desirable feature as 30% of failures of mechanical assist devices result from infection.

The ability to place an individual device adjacent a specific portion of a heart is of great significance especially when it is understood that the chambers of the heart differ considerably in both function and anatomy.

The left ventricle is the chamber of the heart which receives oxygenated blood from the lungs. The function of the left ventricle is to pump this oxygenated blood to the entire body which requires a greater force of ejection. The blood inside the left ventricle is therefore under a greater pressure than in the right ventricle (about six times higher), the right ventricle simply having to pump de-oxygenated blood as far as the lungs. To obtain a sufficient ejection of blood, the muscular wall of the left ventricle must vigorously contract

against the blood filled chamber. Accordingly, the walls of the left ventricle are much thicker and in fact, about three times thicker than the walls of the right ventricle.

If a device is to provide adequate assistance to a failing left ventricle it must apply a sufficient force upon the ventricle to eject a volume of blood at a sufficient pressure to reach the entire body. On the other hand, a failing right ventricle requires much less device force to eject the blood within the chamber to the lungs.

The present invention enables separate and individually controlled devices 10 and 20 to be positioned against the right and the left ventricles. Accordingly, less pressure may be applied to device 10 positioned on the right ventricle 83 than to device 20 positioned on the left ventricle 82.

The anatomy of the left and right ventricular chambers also differs substantially. In cross-section, the left ventricle is circular whereas the right ventricle is crescentic due to the bulging of the interventricular septum (the wall which divides the left and the right ventricles) into the cavity of the right ventricle. The difference in anatomy of the two ventricles calls for a particular structure of device to ensure optimal fit and performance.

Figure 5 shows a device 20 particularly suitable for use in respect of the left ventricle. The device 20 is of the same general structure as device 10 although it is different in shape. Device 20 includes a paddle-like body 21 having a heart compressing wall 22 and a distal wall 23. The walls are curved in a similar fashion to those of device 10. A chamber 25 is disposed between the walls and functions in the same manner as described with reference to device 10.

In use the devices are small enough to be inserted by endoscopic or some other form of minimally invasive surgery. The devices may be made from a material that can adopt several different configurations and in preferred embodiments, the devices may be constructed of a 'shape memory' flexible material such as polyurethane or it may include within its structure a memory shape material, such as a Nitinol™ wire, threaded around its

periphery. The device may be inserted into a cannula or some other delivery device in a closed configuration. The cannula is then introduced into the chest cavity through a puncture or incision and when in position adjacent the portion of heart to be assisted, the paddle is disposed from the end of the cannula. Once free of the cannula, the device takes on an expanded configuration such that the wall is caused to engage with the adjacent portion of heart.

When the device is in place proximate the heart, an elastic mesh (not shown) or other like flexible material may be placed around the heart thereby initially securing the device to the heart surface. The elastic mesh may be removed upon integration of the heart tissue with the device. Alternatively, the mesh may be made from a biodegradable material which over time will be broken down and resorbed by the body.

The heart actuator device as depicted herein may be activated during systole or diastole of the heart or at any other predetermined interval where the heart rhythm is chaotic or absent. The actuator device can be activated in early systole, in mid systole, in late systole, or throughout systole.

The devices 10 and 20 can include a monitoring means that monitors the native electrical activity of the heart of the patient. Such a monitoring means can be an electrocardiogram (ECG). In this case, an ECG electrode 30 or 40 is connected to at least a region of the surface of a heart and the electrical signals received from the ECG electrode transmitted to a cardiotachometer for the detection of heart rate or beat-to-beat interval (in milliseconds) or other electrical activity emanating from the heart. Exponential and derivative enhancement techniques are used to assure discrimination of the ECG's R-wave. Wide dynamic gain range and adjustable latency time prevent false triggering. The natural heart rate is used in a feedback loop to control intensity of heart assist. If predetermined heart rate limits are exceeded the control system automatically switches to fixed rate or variable ratio assist. Specifications of this part of the control system include the following: (1) usable rate range 10 to 500 beats per minute (bpm) (2) usable interval range 1ms to 10s (3) measurement resolution 1ms (interval), 0.1 bpm (rate) (4) latency time adjustment

range from 50ms to ls or more. The monitoring of the heart in this way enables the heart assist device to be activated or deactivated at a particular desired time in the natural cycle of a heart or at a fixed interval in case of a chaotic heart rhythm such as ventricular fibrillation or where there is lack of any intrinsic ventricular rhythm as in asystole.

As shown, each of the devices 10 and 20 may have a plurality of piezoelectric sensors in the form of sonomicrometers 31, 32, 33, 41, 42, 43 which are adapted to measure the heart dimensions and the movement of the device walls during the cardiac cycle. The piezoelectric sensors can be formed from a piezoelectric crystal or piezoelectric plastics material (e.g. polyvinylidene fluoride). In the case of a crystal, the surface area of each sensor is preferably about $1mm^2$. The sensors provide a signal output to a signal receiving means, that like the driver can be located internal or external the body. If required, a power source for the sensors can also be provided internal or external the body. The signals of the sensors can be detected by the signal receiving means using a signal communication system. The communication system could also be used to activate the sensors such that they only provide signal outputs on demand.

If required, the signals once received by the signal receiving means can be transmitted through a data transmission network for analysis at a distal location. For example, a physician could arrange for the download of signals of the sensors of the device of a patient over the data transmission network and provide an analysis of these signals without any requirement for the patient to visit the physician.

The dimensions measured by the sensors might include ventricular dimensions, including end-systolic and end-diastolic dimensions, segmental dimensions and cross-sectional dimensions and movement or displacement characteristics of the devices. By the measurement of such dimensions, the signal receiving means or another device using signals output by the signal receiving means can be used to determine heart performance characteristics, including the ventricular volume, stroke volume, ejection fraction percentage and cardiac output of the heart.

The sensors can be used to monitor variation in heart performance in response to different sequences of deflection of the walls of the devices. This can be used to allow determination of the optimal sequence of deflection of the devices and also allow the device to vary the sequence in response to changes in the heart cycle. The sequence of deflection of the devices can be adjusted in a number of ways, including:

- the ratio of assisted to non-assisted beats; and
- the electromechanical delay between native atrial (electrical) heart activation and deflection of the paddles.

In the case of a chaotic native heart rhythm the actuation can be a fixed pattern or one based on specific predetermined algorithms.

The sensors can be particularly useful in detecting the onset of ventricular fibrillation which can at times be hard to detect with routine ECG signal monitoring.

The signals output by the sensors may also be used to set and adjust the degree of pressurisation of the devices and the rate of rise and decay of pressure in the devices.

Optimisation of the settings of the device pressurisation, preferably in the presence of a physician, can be done in response to (a) exercise performed by the patient, or (b) by pacing the heart using an ECG electrode attached to the heart. The ECG electrode may be typically implanted at the time of device implantation or may be already in place. A pacemaker that is inserted under the skin of the patient can be used to provide the necessary stimulation to the ECG electrode to pace the heart. The electrical stimulation provided by the pacemaker when it is implanted, can also be used as the trigger for the pressurisation sequence of the devices.

Referring to Figure 6, the top panel A, arterial blood pressure (mean 104 mmHg) and aortic blood flow (BF, 4.02L/min) were recorded under normal physiological conditions in a sheep with a device implanted. Referring now to panel B, there is shown the situation after stable heart failure has been induced by intravenous infusion of the beta adrenergic receptor antagonist Esmolol™. Arterial pressure decreased by 36% to 67 mmHg and BF decreased 40% to 2.42 L/min. Finally, panel C illustrates a situation when

the failing heart was assisted by the device pressurised to 140 mmHg for 200 ms, the arterial pressure and BF rose to 90 mmHg and 3.54 L/min respectively.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

THE CLAIMS :

1. A heart actuator device for use in heart assist apparatus, the device including a paddle-like main body, the main body including a heart compressing wall, which in use is adapted to be affixed to at least a region of the heart, and a distal wall, which in use is adapted to be distal that region of the heart, and the heart compressing wall being movable in a direction relatively away from the distal wall, so as, in use to compress at least that region of the heart thereby assisting movement of the heart wall.

2. A device according to claim 1 wherein said paddle like main body includes two major walls secured to or integral with each other at the peripheral portions thereof, one of said major walls defining said heart compressing wall and the other defining said distal wall.

3. A device according to claim 1 or claim 2 wherein said heart compressing wall is generally curved inwardly towards the distal wall when in a normally relaxed condition.

4. A device according to claim 3 wherein the said distal wall is curved outwardly when in a normally relaxed condition.

5. A device according to any preceding claim including a chamber within the main body between the heart compressing wall and said distal wall and being adapted for the ingress or egress of fluid which causes the movement of the heart compressing wall.

6. A device according to any preceding claim wherein said main body is configured such that both the heart compressing wall and the distal wall are adapted to move in a direction relatively away from one another during compression of the heart.

7. A device according to claim 6 wherein the heart compressing wall and the distal wall of the main body are of the materials with different degrees of stiffness.

8. A device according to claim 7 wherein said distal wall includes a reinforcing material therein to provide for a greater degree of stiffness relative to the heart compressing wall.

9. A device according to claim 8 wherein said reinforcing material extends through the peripheral portions of device into the heart compressing wall.

10. device according to claim 8 or 9 wherein the reinforcing material is Dacron ™ mesh.

11. A device according to any preceding claim wherein at least a portion of the heart compressing wall includes a biointegratable material surface which facilitates the ingrowth of vascularised cellular tissue elements into the wall, the ingrowth of tissue into the heart compressing surface serving to affix the heart compressing wall of the main body to the heart.

12. A device according to claim 11 wherein the distal wall includes a biointegratable material that promotes vascularised cellular ingrowth into said distal wall so that it integrates into surrounding tissue.

13. A device according to claim 10 or claim 11 wherein the biointegratable material is in the form of woven Tecoflex™ mesh, Seare Biomatrix™, or Gore-Tex DualMesh ™.

14. A device according to any preceding claim wherein the paddle-like main body is deformable so as to be capable of undergoing a change from a first configuration to a second configuration, said paddle-like main body including a shape memory material which permits said deformation and subsequent return to its original shape.

15. A device according to any preceding claim wherein the main body includes a unitary structure formed of polyurethane or silicone, including reinforcement mesh or hardened material.

16. A device according to any preceding claim including means to monitor the electrical and mechanical activity of the heart.

17. A device according to claim 16 wherein the device is activated so as to boost the pump output of the heart.

18. A device according to claim 17 wherein said monitoring means includes an electrocardiogram electrode operatively connected to at least a region of the surface of the heart and the electrical signals received from the electrodes are used to monitor the intrinsic electrical activity of the heart, theses signals being also transmitted to a cardiotachometer for the detection of heart rate or beat-to-beat interval.

19. A device according to any preceding claim including a plurality of sensors adapted to measure the heart dimensions and movement or displacement of the chamber walls during excursion of the devices.

20. A device according to claim 19 wherein each sensor is a piezoelectric sensor.

21. A device according to claim 20 wherein each sensor is a sonomicrometer.

22. A device according to claim 18 wherein said ECG electrode is integrated into said heart compressing wall.

23. A device according to claim 19, 20 and 21 wherein there are a plurality of said sensors operatively connected in selective positions to said heart compressing wall.

24. A device according to any preceding claim wherein said heart compressing wall is configured so that the heart compressing surface generally conforms to the shape of that region of the heart to which it is fixed.

25. A device according to any preceding claim wherein said heart compressing wall is adapted to be affixed to a region of the left ventricle of the heart.

26. A device according to anyone of claims 1 to 25 wherein said heart compressing wall is adapted to be fixed to a region the right ventricle of the heart.

27. A device according to any preceding claim wherein the main body is at least initially affixed to the heart by straps.

28. Heart assist apparatus including one or more heart actuator devices according to any preceding claim which are adapted to be secured to a region or selected regions of the heart, said apparatus further including driving means in fluid communication with the chamber, said driving means including a controller and a power source.

29. Apparatus according to claim 28 wherein said driving means is a hydraulic driving means.

30. Apparatus according to claim 28 wherein said driving means is a pneumatic driving means.

31. Apparatus according to claim 28, 29 or 30 wherein there is provided a plurality of said heart actuator devices operatively connected to selected regions of the heart.

32. A method of assisting a failing heart using a heart actuator device according to any one of claims 1 to 27, the method including the steps of:

(a) positioning the heart compressing wall of the device at least adjacent a region of the heart;

(b) affixing the heart compressing wall with the region of the heart: and

(c) applying fluid pressure to the chamber of the device such that the heart compressing wall compresses the heart wall in the region of the heart to which the device is affixed.

33. A method of introducing a device according to any one of claims 1 to 27 to the heart of a patient, the method including the steps of:

(a) making an incision or puncture in the chest of a patient to allow access to the heart;

(b) inserting the device through the incision or puncture;

(c) affixing the heart compressing wall to a region of the heart; and

(d) applying fluid pressure to the chamber of the device such that the heart compressing wall compresses the heart wall in the region of the heart to which the device is affixed.

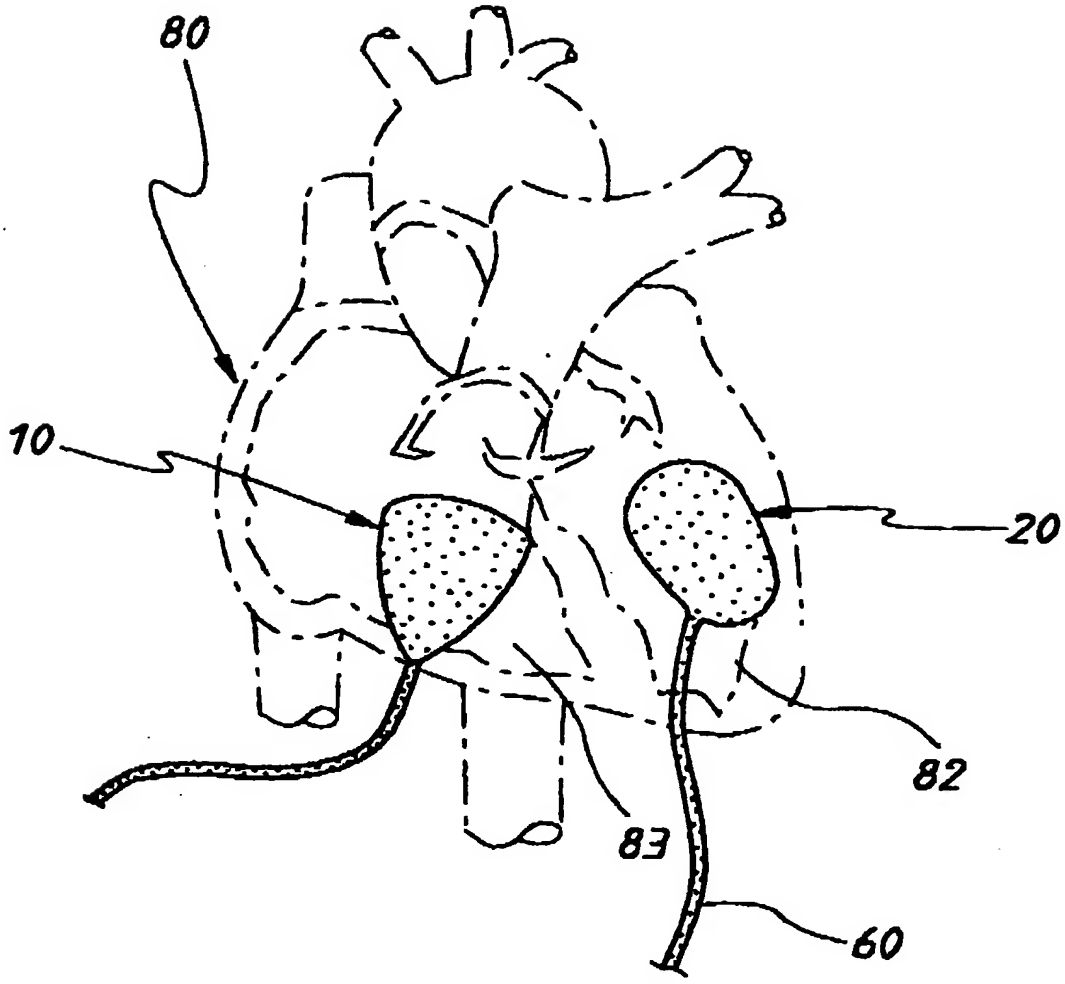

FIG. 1

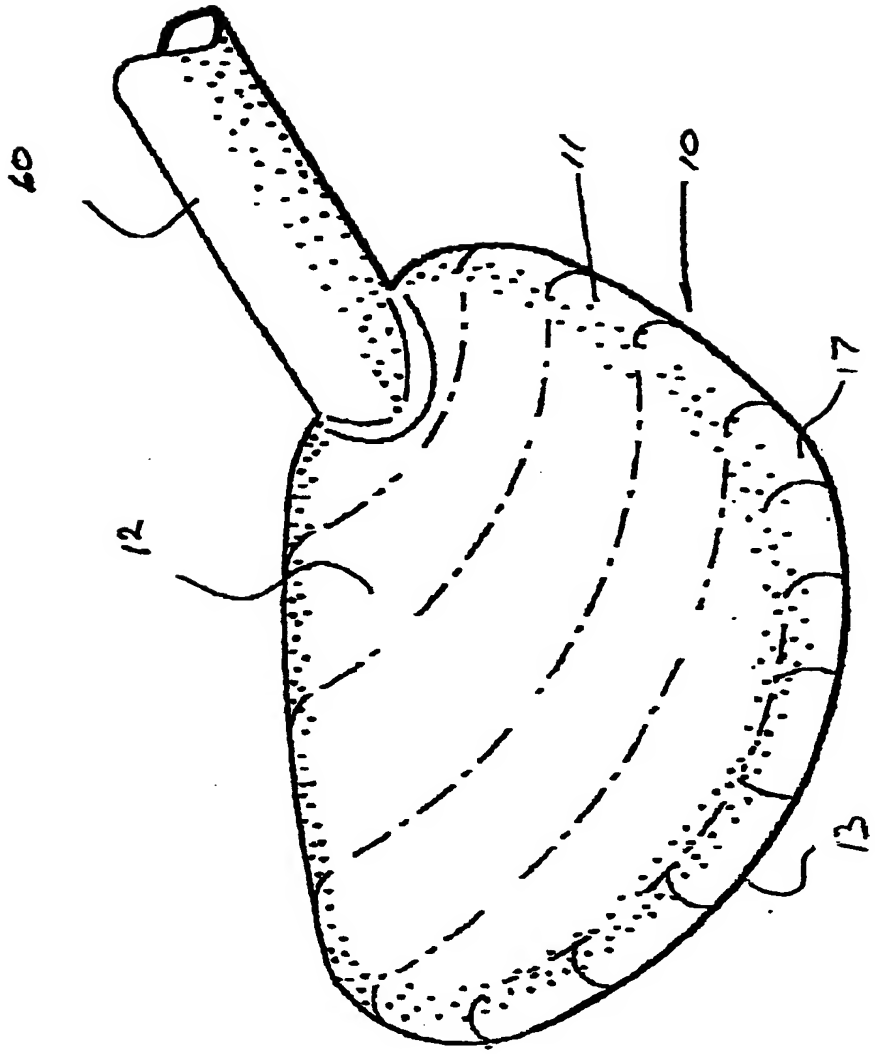

FIG.2

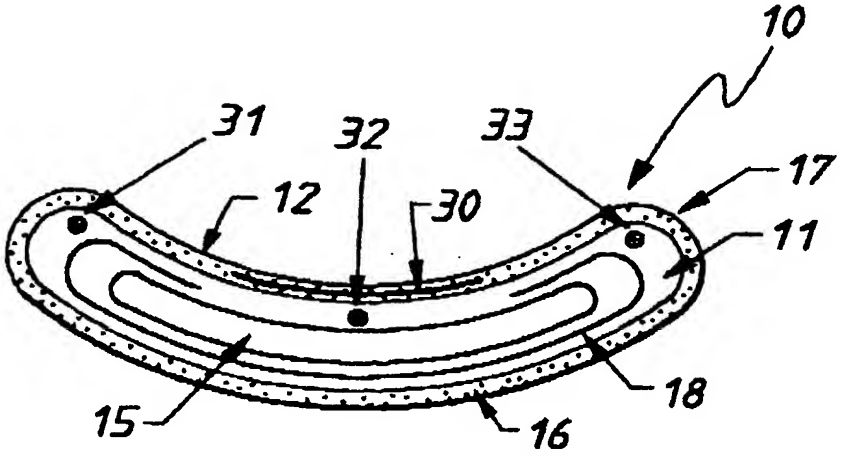

FIG.3

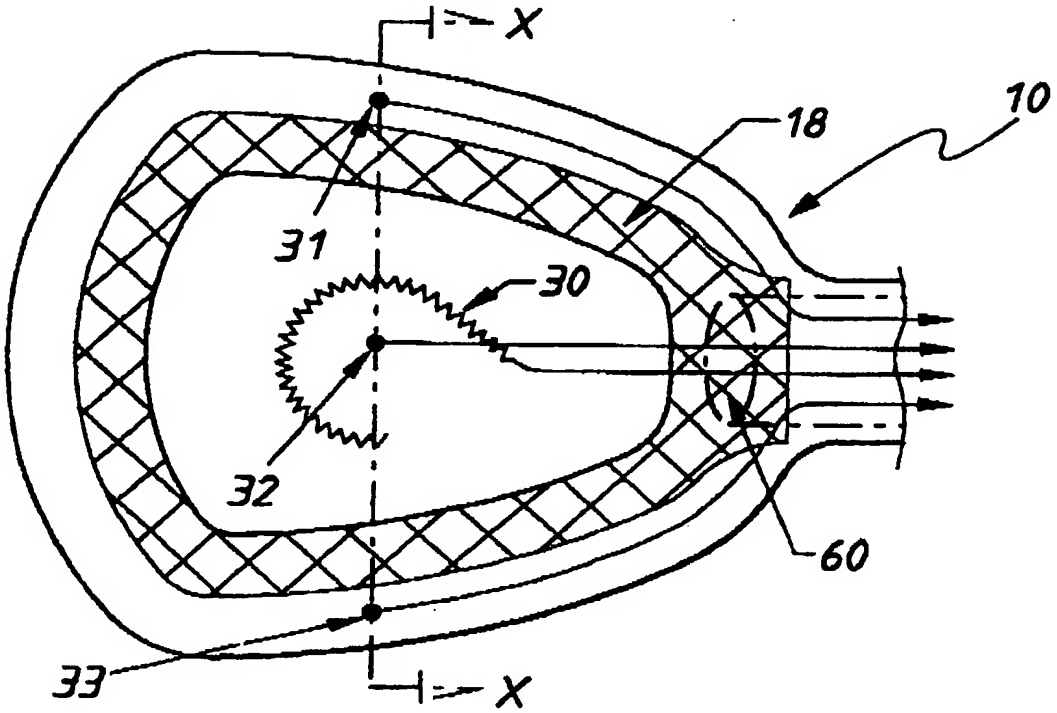

FIG.4

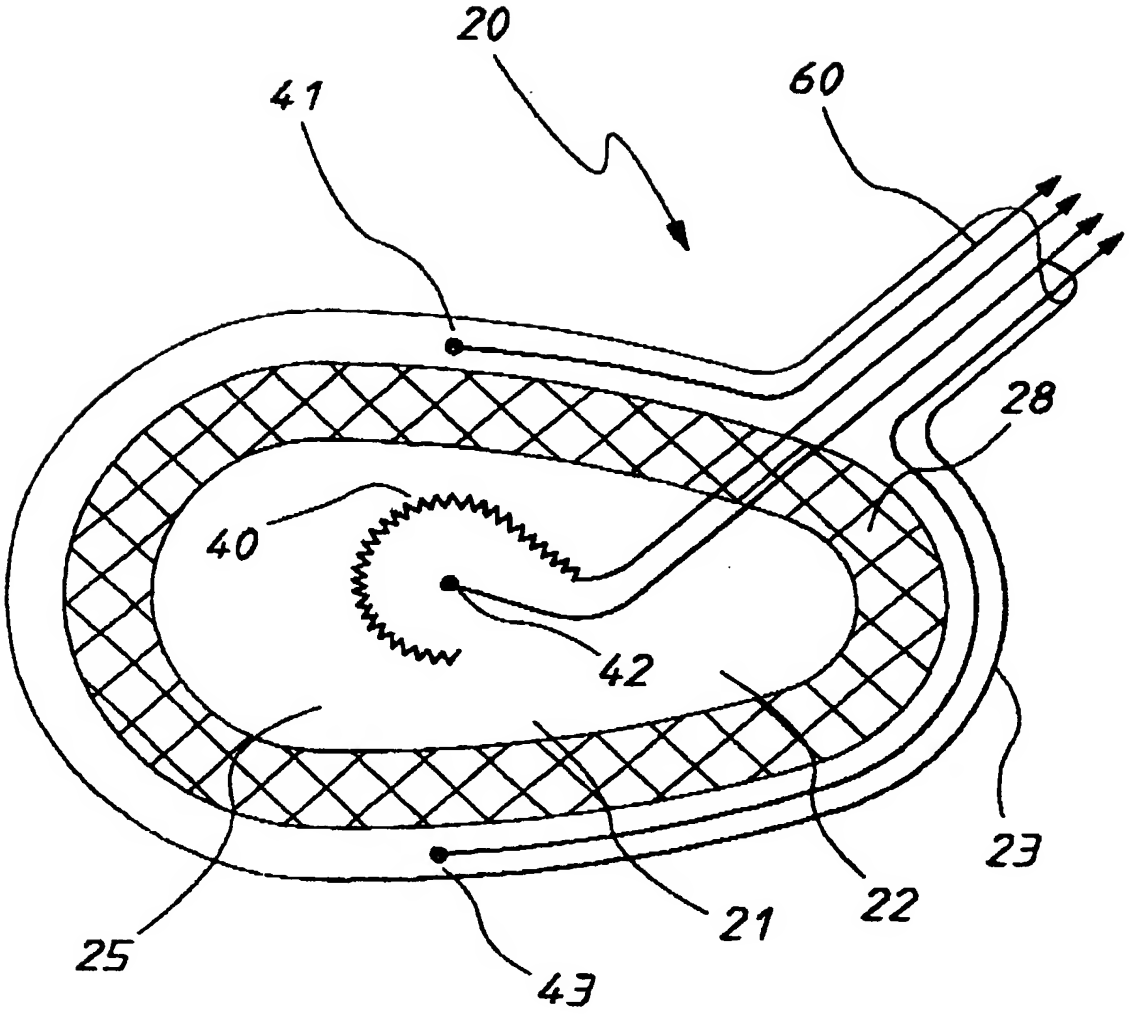

FIG.5

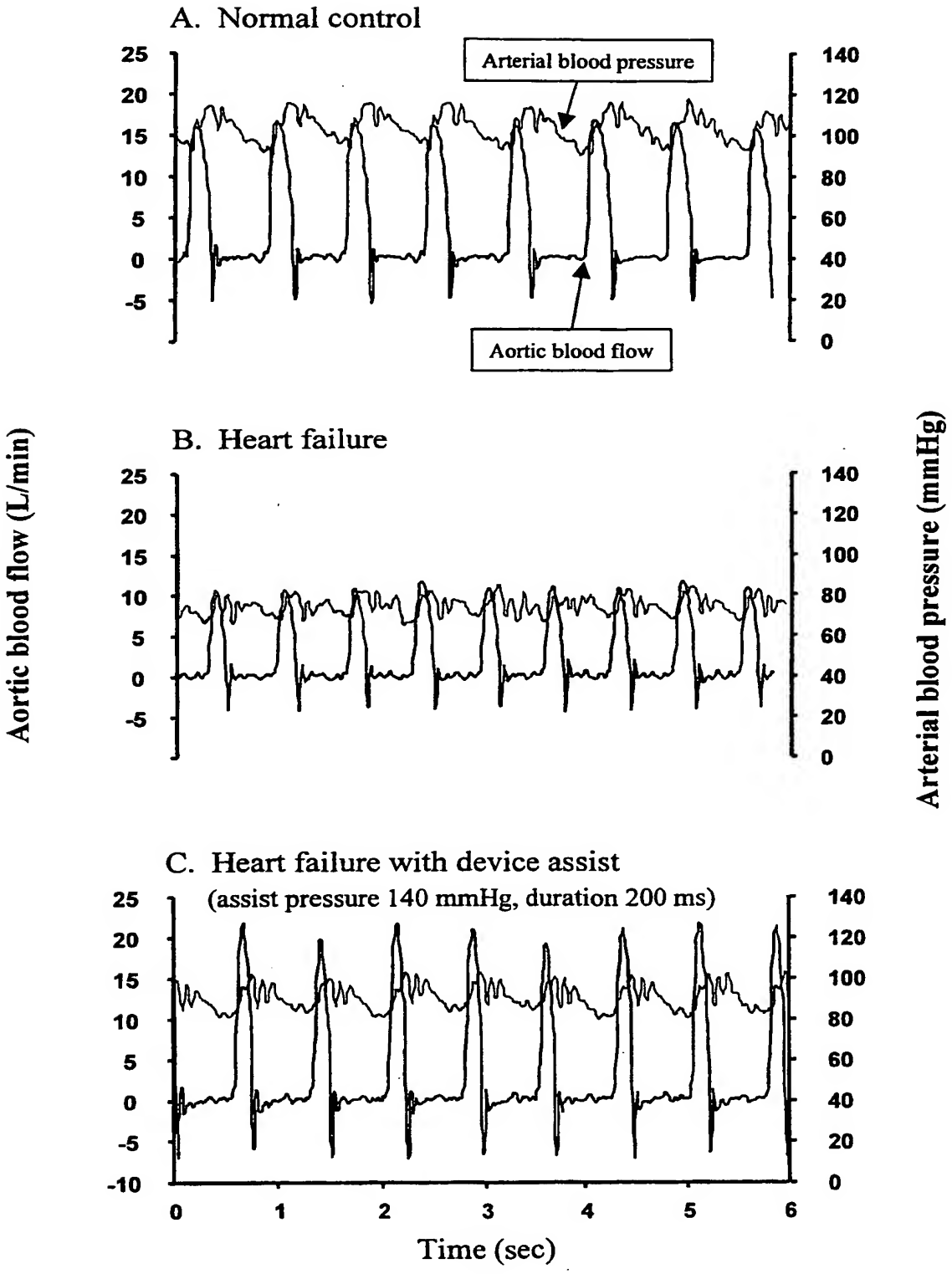
A. Normal control
Arterial blood pressure
Aortic blood flow
B. Heart failure
C. Heart failure with device assist
(assist pressure 140 mmHg, duration 200 ms)
Aortic blood flow (L/min)
Arterial blood pressure (mmHg)
Time (sec)
25
20
15
10
5
0
-5
-10
140
120
100
80
60
40
20
0
1
2
3
4
5
6

FIG.6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00665

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 1/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
KEYWORDS

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98/55165 (Woodard) 10 December 1998 Figures 6, 11-12; abstract	
A	US 5169381 (Snyders) 8 December 1992 Figure 4; abstract	
A	US 5749839 (Kovacs) 12 May 1998 Figure 1; abstract	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 August 2000	31 AUG 2000
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer ROSEMARY LONGSTAFF Telephone No : (02) 6283 2637

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00665

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5098369 (Heilman et al.) 24 March 1992 Figures 1, 3; abstract	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00665

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	9855165	AU	77517/98	EP	1007112		
US	5169381	NONE					
US	5749839	US	5738627	US	5908378		
US	5098369	EP	280301	EP	583012	JP	63294865
		US	4925443				

END OF ANNEX

Copy for the Elected Office (EO/AU)

PCT/AU00/00665

PATENT COOPERATION TREATY

COPY

5/993/00

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

Doq.

DAVIES COLLISON CAVE
Anthony Smeeton
Level 10, 10 Barrack Street
Sydney, NSW 2000
AUSTRALIE

DCC (Sydney) Mail Rcvd
22 OCT 2001
Action processed by lm
on 23/10/01
Action Amr records reflect new name address

Date of mailing (day/month/year)	IMPORTANT NOTIFICATION
17 September 2001 (17.09.01)	
Applicant's or agent's file reference 7485730/ARS	
International application No. PCT/AU00/00665	**International filing date** (day/month/year) 15 June 2000 (15.06.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address

NORTHERN SYDNEY AREA HEALTH SERVICE
Block 4, Level 3
Royal North Shore Hospital
St Leonards, NSW 2065
Australia

State of Nationality: AU
State of Residence: AU
Telephone No.: 61 2 9926 7845
Facsimile No.: 61 2 9901 4097
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address

HEART ASSIST TECHNOLOGIES PTY LTD.
Block 4, Level 3
Royal North Shore Hospital
St Leonards, NSW 2065
Australia

State of Nationality: AU
State of Residence: AU
Telephone No.: 61 2 9926 7845
Facsimile No.: 61 2 9901 4097
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Mougamadou ABIDINE (Fax 338.87.40)
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

004290593

- 8 OCT 2001

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

DAVIES COLLISON CAVE
Anthony Smeeton
Level 10, 10 Barrack Street
Sydney, NSW 2000
AUSTRALIE

Date of mailing (day/month/year)
17 September 2001 (17.09.01)

Applicant's or agent's file reference
7485730/ARS

IMPORTANT NOTIFICATION

International application No.
PCT/AU00/00665

International filing date (day/month/year)
15 June 2000 (15.06.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
NORTHERN SYDNEY AREA HEALTH SERVICE
Block 4, Level 3
Royal North Shore Hospital
St Leonards, NSW 2065
Australia

State of Nationality: AU
State of Residence: AU
Telephone No.: 61 2 9926 7845
Facsimile No.: 61 2 9901 4097
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
HEART ASSIST TECHNOLOGIES PTY LTD.
Block 4, Level 3
Royal North Shore Hospital
St Leonards, NSW 2065
Australia

State of Nationality: AU
State of Residence: AU
Telephone No.: 61 2 9926 7845
Facsimile No.: 61 2 9901 4097
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Mougamadou ABIDINE (Fax 338.87.40)
Telephone No.: (41-22) 338.83.38

PA... ...T COOPERATION TREAT...

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

DAVIES COLLISON CAVE
Anthony Smeeton
Level 10, 10 Barrack Street
Sydney, NSW 2000
AUSTRALIE

Date of mailing (day/month/year)
29 March 2001 (29.03.01)

Applicant's or agent's file reference
7485730/ARS

IMPORTANT NOTIFICATION

International application No.
PCT/AU00/00665

International filing date (day/month/year)
15 June 2000 (15.06.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
NORTHERN SYDNEY AREA HEALTH SERVICE
Block 4, Level 3
St Leonards, NSW 2065
Australia

State of Nationality: AU
State of Residence: AU
Telephone No.: 61 2 9926 7845
Facsimile No.: 61 2 9901 4097
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
NORTHERN SYDNEY AREA HEALTH SERVICE
Block 4, Level 3
Royal North Shore Hospital
St Leonards, NSW 2065
Australia

State of Nationality: AU
State of Residence: AU
Telephone No.: 61 2 9926 7845
Facsimile No.: 61 2 9901 4097
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
F. Baechler

Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

003931321

F TENT COOPERATION TREA Y

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 30 January 2001 (30.01.01)	
International application No. PCT/AU00/00665	**Applicant's or agent's file reference** 7485730/ARS
International filing date (day/month/year) 15 June 2000 (15.06.00)	**Priority date** (day/month/year) 17 June 1999 (17.06.99)
Applicant HUNYOR, Stephen, Nicholas et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

21 December 2000 (21.12.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer R. E. Stoffel
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

AU0000665

Hunyor et al

PATENT COOPERATION TREA

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
7485730		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/AU00/00665	15 June 2000	17 June 1999

Applicant

NORTHERN SYDNEY AREA HEALTH SERVICE et al

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

[ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

[X] the text is approved as ~~submitted by the applicant~~.

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

[X] as suggested by the applicant.

[ ] None of the figures

[ ] because the applicant failed to suggest a figure

[ ] because this figure better characterizes the invention

FIV

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF RECEIPT OF RECORD COPY

(PCT Rule 24.2(a))

To:

DAVIES COLLISON CAVE
Anthony Smeeton
Level 10, 10 Barrack Street
Sydney, NSW 2000
AUSTRALIE

Date of mailing (day/month/year)	IMPORTANT NOTIFICATION
02 August 2000 (02.08.00)	
Applicant's or agent's file reference	**International application No.**
7485730/ARS	PCT/AU00/00665

The applicant is hereby notified that the International Bureau has received the record copy of the international application as detailed below.

Name(s) of the applicant(s) and State(s) for which they are applicants:

NORTHERN SYDNEY AREA HEALTH SERVICE (for all designated States except US)
HUNYOR, Stephen, Nicholas et al (for US)

International filing date	:	15 June 2000 (15.06.00)
Priority date(s) claimed	:	17 June 1999 (17.06.99)
Date of receipt of the record copy by the International Bureau	:	03 July 2000 (03.07.00)
List of designated Offices	:	

AP :GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZW
EA :AM,AZ,BY,KG,KZ,MD,RU,TJ,TM
EP :AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE
OA :BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG
National :AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,DZ,EE,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KP,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,MZ,NO,NZ,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,US,UZ,VN,YU,ZA,ZW

ATTENTION

The applicant should carefully check the data appearing in this Notification. In case of any discrepancy between these data and the indications in the international application, the applicant should immediately inform the International Bureau.

In addition, the applicant's attention is drawn to the information contained in the Annex, relating to:

- [X] time limits for entry into the national phase
- [ ] confirmation of precautionary designations
- [X] requirements regarding priority documents

A copy of this Notification is being sent to the receiving Office and to the International Searching Authority.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer:

Aino Metcalfe

Telephone No. (41-22) 338.83.38

WO 00/78375
PCT/AU00/0066

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
DAVIES COLLISON CAVE
Anthony Smeeton
Level 10, 10 Barrack Street
Sydney, NSW 2000
AUSTRALIE

Date of mailing (day/month/year) 28 December 2000 (28.12.00)	
Applicant's or agent's file reference 7485730/ARS	**IMPORTANT NOTICE**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/AU00/00665	15 June 2000 (15.06.00)	17 June 1999 (17.06.99)

Applicant
NORTHERN SYDNEY AREA HEALTH SERVICE et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   AG,AU,DZ,KP,KR,MZ,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,
   GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,
   NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW
   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   28 December 2000 (28.12.00) under No. WO 00/78375

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

DAVIES COLLISON CAVE
Anthony Smeeton
Level 10, 10 Barrack Street
Sydney, NSW 2000
AUSTRALIE

Date of mailing (day/month/year) 13 October 2000 (13.10.00)	
Applicant's or agent's file reference 7485730/ARS	**IMPORTANT NOTIFICATION**
International application No. PCT/AU00/00665	International filing date (day/month/year) 15 June 2000 (15.06.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 17 June 1999 (17.06.99)
Applicant NORTHERN SYDNEY AREA HEALTH SERVICE et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
17 June 1999 (17.06.99)	PQ 1006	AU	03 July 2000 (03.07.00)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Khemais BRAHMI

Telephone No. (41-22) 338.83.38

TONY

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

INFORMATION CONCERNING ELECTED OFFICES NOTIFIED OF THEIR ELECTION

(PCT Rule 61.3)

To:

DAVIES COLLISON CAVE
Anthony Smeeton
Level 10, 10 Barrack Street
Sydney, NSW 2000
AUSTRALIE

Date of mailing (day/month/year) 30 January 2001 (30.01.01)	
Applicant's or agent's file reference 7485730/ARS	IMPORTANT INFORMATION

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/AU00/00665	15 June 2000 (15.06.00)	17 June 1999 (17.06.99)

Applicant
NORTHERN SYDNEY AREA HEALTH SERVICE et al

1. The applicant is hereby informed that the International Bureau has, according to Article 31(7), notified each of the following Offices of its election:

   AP :GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZW
   EP :AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE
   National :AU,BG,CA,CN,CZ,DE,IL,JP,KP,KR,MN,NO,NZ,PL,RO,RU,SE,SK,US

2. The following Offices have waived the requirement for the notification of their election; the notification will be sent to them by the International Bureau only upon their request:

   EA :AM,AZ,BY,KG,KZ,MD,RU,TJ,TM
   OA :BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG
   National :AE,AG,AL,AM,AT,AZ,BA,BB,BR,BY,CH,CR,CU,DK,DM,DZ,EE,ES,FI,GB,GD, GE,GH,GM,HR,HU,ID,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MW,MX, MZ,PT,SD,SG,SI,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

3. The applicant is reminded that he must enter the "national phase" **before the expiration of 30 months from the priority date** before each of the Offices listed above. This must be done by paying the national fee(s) and furnishing , if prescribed, a translation of the international application (Article 39(1)(a)), as well as, where applicable, by furnishing a translation of any annexes of the international preliminary examination report (Article 36(3)(b) and Rule 74.1).

   Some offices have fixed time limits expiring later than the above-mentioned time limit. For detailed information about the applicable time limits and the acts to be performed upon entry into the national phase before a particular Office, see Volume II of the PCT Applicant's Guide.

   The entry into the European regional phase is postponed **until 31 months from the priority date** for all States designated for the purposes of obtaining a European patent.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer:
R. E. Stoffel

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 7485730	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU00/00665**	International Filing Date *(day/month/year)* 15 June 2000	Priority Date *(day/month/year)* 17 June 1999

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] A61M 1/12

Applicant

NORTHERN SYDNEY AREA HEALTH SERVICE et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
21 December 2000	5 January 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **SEAN APPLEGATE** Telephone No. (02) 6283 2207

I. Basis of the report

1. With regard to the **elements** of the international application:*

- [X] the international application as originally filed.
- [ ] the description, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the claims, pages , as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the drawings, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

- [ ] contained in the international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims **1-33**	**YES**
	Claims **None**	**NO**
Inventive step (IS)	Claims **1-33**	**YES**
	Claims **None**	**NO**
Industrial applicability (IA)	Claims **1-33**	**YES**
	Claims **None**	**NO**

2. Citations and explanations (Rule 70.7)

(a) WO 98/55165 (Woodard) 10 December 1998.

(b) US 5169381 (Snyders) 8 December 1992.

(c) US 5749839 (Kovacs) 12 May 1998.

(d) US 5098369 (Heilman et al.) 24 March 1992.

The heart actuator device defined in claims 1-33 satisfies the requirements of novelty and inventive step when compared with documents (a) to (d) above. None of these documents when considered either alone or in obvious combination discloses a device with all of the features defined.

7485730/ARS

PCT REQUEST

Original (for SUBMISSION) - printed on 15.06.2000 11:24:38 AM

0 0-1	For receiving Office use only International Application No.	
0-2	International Filing Date	
0-3	Name of receiving Office and "PCT International Application"	
0-4 0-4-1	Form - PCT/RO/101 PCT Request Prepared using	PCT-EASY Version 2.90 (updated 10.05.2000)
0-5	Petition The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	Receiving Office (specified by the applicant)	Australian Patent Office (RO/AU)
0-7	Applicant's or agent's file reference	7485730/ARS
I	Title of invention	AN ASSIST DEVICE FOR THE FAILING HEART
II II-1 II-2 II-4 II-5 II-6 II-7 II-8 II-9	Applicant This person is: Applicant for Name Address: State of nationality State of residence Telephone No. Facsimile No.	applicant only all designated States except US NORTHERN SYDNEY AREA HEALTH SERVICE Block 4, Level 3 ST LEONARDS, New South Wales 2065 Australia AU AU 61 2 9926 7845 61 2 9901 4097
III-1 III-1-1 III-1-2 III-1-4 III-1-5 III-1-6 III-1-7	Applicant and/or inventor This person is: Applicant for Name (LAST, First) Address: State of nationality State of residence	applicant and inventor US only HUNYOR, Stephen, Nicholas 119 St Johns Avenue GORDON, New South Wales 2032 Australia AU AU

PCT REQUEST

7485730/ARS

Original (for SUBMISSION) - printed on 15.06.2000 11:24:38 AM

III-2	**Applicant and/or inventor**	
III-2-1	This person is:	applicant and inventor
III-2-2	Applicant for	US only
III-2-4	Name (LAST, First)	PLEKHANOV, Serguei, Michael
III-2-5	Address:	10/17 Dural Street HORNSBY, New South Wales 2077 Australia
III-2-6	State of nationality	AU
III-2-7	State of residence	AU
III-3	**Applicant and/or inventor**	
III-3-1	This person is:	applicant and inventor
III-3-2	Applicant for	US only
III-3-4	Name (LAST, First)	HUANG, Yifei
III-3-5	Address:	30/2 McMillian Road ARTARMON, New South Wales 2064 Australia
III-3-6	State of nationality	AU
III-3-7	State of residence	AU
IV-1	**Agent or common representative; or address for correspondence** The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	agent
IV-1-1	Name	DAVIES COLLISON CAVE
IV-1-2	Address:	Anthony Smeeton Level 10, 10 Barrack Street SYDNEY, New South Wales 2000 Australia
IV-1-3	Telephone No.	61 2 9262 2611
IV-1-4	Facsimile No.	61 2 9262 1080
IV-1-5	e-mail	tsmeeton@davies.com.au
V	**Designation of States**	
V-1	Regional Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AP: GH GM KE LS MW MZ SD SL SZ TZ UG ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT EP: AT BE CH&LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE and any other State which is a Contracting State of the European Patent Convention and of the PCT OA: BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT

PCT REQUEST 7485730/ARS

Original (for SUBMISSION) - printed on 15.06.2000 11:24:38 AM

V-2	National Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AE AG AL AM AT AU AZ BA BB BG BR BY CA CH&LI CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW	
V-5	**Precautionary Designation Statement** In addition to the designations made under items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.		
V-6	**Exclusion(s) from precautionary designations**	NONE	
VI-1	**Priority claim of earlier national application**		
VI-1-1	Filing date	17 June 1999 (17.06.1999)	
VI-1-2	Number	PQ1006	
VI-1-3	Country	AU	
VI-2	**Priority document request** The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):	VI-1	
VII-1	**International Searching Authority Chosen**	Australian Patent Office (ISA/AU)	
VIII	**Check list**	number of sheets	electronic file(s) attached
VIII-1	Request	4	-
VIII-2	Description	16	-
VIII-3	Claims	5	-
VIII-4	Abstract	1	7485730.txt
VIII-5	Drawings	5	-
VIII-7	TOTAL	31	
	Accompanying Items	paper document(s) attached	electronic file(s) attached
VIII-8	Fee calculation sheet	✓	-
VIII-16	PCT-EASY diskette	-	diskette
VIII-18	**Figure of the drawings which should accompany the abstract**	1	
VIII-19	**Language of filing of the international application**	English	
IX-1	**Signature of applicant or agent**		
IX-1-1	Name	DAVIES COLLISON CAVE	
IX-1-2	Name of signatory	Anthony Smeeton	

PCT REQUEST

7485730/ARS

Original (for SUBMISSION) - printed on 15.06.2000 11:24:38 AM

FOR RECEIVING OFFICE USE ONLY

10-1	Date of actual receipt of the purported international application	
10-2	Drawings:	
10-2-1	Received	
10-2-2	Not received	
10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/AU
10-6	Transmittal of search copy delayed until search fee is paid	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	Date of receipt of the record copy by the International Bureau	

The demand must be filed directly with the competent International Preliminary Examining Authority; if two or more Authorities are competent, with the one chosen by the applicant. The name or two-letter code of that Authority may be indicated by the applicant on the line below.

IPEA/_____

PCT

CHAPTER II

DEMAND

Under Article 31 of the Patent Cooperation Treaty:
The Undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA	Date of receipt of DEMAND

Box No. 1 IDENTIFICATION OF THE INTERNATIONAL APPLICATION

Applicant's or agent's file reference: 7485730/ARS

International application No.	International filing date (*day/month/year*)	(Earliest) Priority date (*day/month/year*)
PCT/AU00/00665	15 June, 2000	17 June, 1999

Title of invention

An assist device for the failing heart

Box No. II APPLICANT(S)

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

Northern Sydney Area Health Service
Block 4, Level 3, Royal North Shore Hospital, St Leonards, New South Wales 2065, Australia

Telephone No.:

Facsimile No.:

Email.: mail@davies.com.au

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
AUSTRALIA	AUSTRALIA

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

HUNYOR, Stephen Nicholas
119 St Jones Avenue
GORDON, New South Wales, 2032, Australia

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
AUSTRALIA	AUSTRALIA

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:	State *(that is, country)* of residence:

[X] Further applicants are indicated on a continuation sheet.

International application no.
PCT/AU00/00665

Continuation of Box No. II APPLICANT(S)

If none of the following sub-boxes is used, this sheet should not be included in the demand.

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

PLEKHANOV, Surguei Michael
10/17 Dural Street
HORNSBY, New South Wales, 2077, Australia

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
AUSTRALIA	AUSTRALIA

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:	State *(that is, country)* of residence:

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:	State *(that is, country)* of residence:

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:	State *(that is, country)* of residence:

☐ Further applicants are indicated on another continuation sheet.

International application no.
PCT/AU00/00665

Box No. III AGENT OR COMMON REPRESENTATIVE: OR ADDRESS FOR CORRESPONDENCE

The following person is [X] agent [ ] common representative

and [X] has been appointed earlier and represents the applicant(s) also for international preliminary examination.

[ ] is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

[ ] is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

SMEETON, Anthony Richard

DAVIES COLLISON CAVE
Level 10
10 Barrack Street
SYDNEY NSW 2000

Telephone No.: 02 9262 2611

Facsimile No.: 02 9262 1080

Teleprinter No.:

[ ] **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

Statement concerning amendments:*

1. The applicant wishes the international preliminary examination **to start on the basis of:**

[X] the international application as originally filed

the description [ ] as originally filed
[ ] as amended under Article 34

the claims [ ] as originally filed
[ ] as amended under Article 19 (together with any accompanying statement)
[ ] as amended under Article 34

the drawings [ ] as originally filed
[ ] as amended under Article 34

2. [ ] The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. [ ] The applicant wishes the start of the international preliminary examination **to be postponed** until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69. 1(d)). *This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

- Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: ENGLISH

[X] which is the language in which the international application was filed.
[ ] which is the language of a translation furnished for the purposes of international search.
[ ] which is the language of publication of the international application.
[ ] which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby **elects all eligible States** *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

Excluding the following States which the applicant wishes **not to elect:**

International application no.
PCT/AU00/00665

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

				For International Preliminary Examining Authority use only	
				received	not received
1.	translation of international application	:	sheets	☐	☐
2.	amendments under Article 34	:	sheets	☐	☐
3.	copy (or, where required, translation) of amendments under Article 19	:	sheets	☐	☐
4.	copy (or, where required, translation) of statement under Article 19	:	sheets	☐	☐
5.	letter	:	sheets	☐	☐
6.	other *(specify)*	:	sheets	☐	☐

The demand is also accompanied by the item(s) marked below:

1. [x] fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney: reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ nucleotide and or amino acid sequence listing in computer readable form
6. ☐ other *(specify)*:

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

SMEETON, Anthony Richard
For and on behalf of
the applicant/s

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. ☐ The applicant has been informed accordingly.

4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority dated as extended by virtue of Rule 80.5.

5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority dated, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

See Notes to the demand form